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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,351	SIMON, BRUCE J.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007 and 21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-18* is/are pending in the application.

4a) Of the above claim(s) *6-8,13 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,10,12,14-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/26/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments filed November 26, 2007, and April 21, 2008, have been received and entered.

Claims 15-18 are new. Claim 11 is cancelled. Claims 1-10 and 12-18 are pending.

Election/Restrictions

Applicant's election with traverse of Group I, collagen from claim 12, and growth factors from claim 14, in the reply filed on April 30, 2007, was acknowledged in the 8/24/07 office action.

Applicant's election with traverse of endothelial cells in the reply filed on April 21, 2008 is acknowledged. The traversal is on the ground(s) that claims 16, 17 and 18 are merely species of a method that can be used for treatment of any of a variety of wound or bone defects and thus there is a common inventive concept. This is not found persuasive because each different type of cell would be used for treating a different bone/wound defect, which have different characteristics and treatment requirements.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-8, 13, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 1-5, 9, 10, 12, 14-16, and 18 are examined on the merits to the extent they read on the elected subject matter and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 9, 10, 12, 14-16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claims 1 and 15 recite that the medium is capable of inducing regeneration of at least cell type which provides a therapeutic effect in or near a tissue defect, which is considered new matter. The specification does not speak of the regeneration of cells. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Claims 1-5, 9-12, 14-16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding undue experimentation, *In re Wands*, 8 USPQ2d 1400, at 1404 (Fed. Cir. 1988) states:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (Citations omitted).

The claims are very broad in that they encompass methods and compositions for treating any tissue defect in a human or other animal subject. Further still, the specification defines "tissue defect" broadly as "any condition involving tissue which is inadequate for physiological or cosmetic purposes (page 4, lines 3-5). Thus, the complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. Moreover, there is a clear absence of working examples, as none of the examples in the specification provide any data to demonstrate the effectiveness of the instant invention in treating any tissue defect. Examples 1 and 2 in the specification appear to be prophetic examples. Finally, one would need to perform a large quantity of experimentation to identify all tissue cultures exposed to an electromagnetic field which result in media which are effective in treating all tissue defects, of which there are many types with complex and different characteristics.

In view of the breadth of the claims and the lack of guidance provided by the specification, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1-5, 9-12, 14-16, and 18 are not considered enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Baylink (US 5,195,940).

Baylink discloses that "…the production of growth factor can be increased in vivo by the exogenous stimulation of living tissue with magnetic fields" (column 1, lines 53-55). Baylink teaches stimulating the production of growth factor in living tissue by the application of a magnetic field (abstract). The magnetic field may be applied with an electromagnet (column 6, lines 50-51), and thus Baylink teaches the application of electromagnetic fields for enhanced growth factor production. Baylink emphasizes that "it is to be understood that the method of the present invention is suitable for use in stimulating growth factor in a range of living tissue, including but not limited to **in vitro cell cultures**, animal subjects, or human subjects" (column 5, lines 28-32, emphasis added). Example 1 at column 13 of the Baylink patent teaches a tissue culture of human osteosarcoma cells grown in DMEM medium which is subjected to a magnetic field (specifically, column 13, lines 11-15). The culture media were collected after magnetic field exposure (column 13, lines 21-23) and have increased production of growth factor (column 13, lines 57-60). Note that the DMEM medium can be considered a "pharmaceutically-acceptable carrier."

Although the reference does not specifically teach that the composition is effective for the treatment of tissue defects in a human or other animal subject, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable".

A holding of anticipation is clearly required.

Claims 9, 11, and 14 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by George et al. (US 6,334,069).

George et al. discloses the use of an electromagnetic field of specified strength and duration "...to stimulate cellular growth and proliferation,...growth factor expression,...and reductions in cell doubling time" (column 9, lines 12-17). George et al. accomplishes this by the administration of pulsed electromagnetic energy to cells (column 10, lines 4-7).

Example 1 in column 18 of the George patent describes the treatment of a fibroblast tissue culture with pulsed electromagnetic energy. The whole culture can be considered a composition comprising medium produced by electromagnetic stimulation of a tissue culture. Further still, Dulbecco's modified Eagle's medium present in the whole culture can be considered a "pharmaceutically-acceptable carrier."

Although the reference does not specifically teach that the composition is effective for the treatment of tissue defects in a human or other animal subject, the compositions are the same,

thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable".

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9, 10, 12, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al. (US 6,372,494) in view of Baylink (US 5,195,940) and/or George et al. (US 6,334,069), and further in view of Guerkov et al. (Clinical Orthopaedics and Related Research. 2001. 384: 265-279).

Naughton et al. discloses conditioned cell medium compositions which are conditioned using any eukaryotic cell type (abstract). A culture medium is incubated with cells in order to obtain a "conditioned cell medium" (column 1, lines 30-32). The culture medium may be conditioned by stromal cells preferably in a three dimensional tissue construct (column 4, lines 49-53), which can be further cultured with parenchymal cells (column 5, lines 4-8). The stromal

cells that can be cultured can include endothelial cells (column 12, lines 46-49), as required by instant claims 2, 10, and 18.

Additionally, "the cells can be cultured by any means known in the art" (column 19, line 62) and once the culture medium is conditioned so that the extracellular proteins such as growth factors have reached desirable levels in the media, the conditioned medium is pumped out of the culturing system and processed for use (column 20, lines 15-19). It is noted in Naughton et al. that "...the conditioned media provided by the present invention is also useful in the treatment of other types of tissue damage, e.g. traumatic or congenital, wherein the repair and/or regeneration of tissue defects or damage is desired since many of these growth factors are found in Applicants' conditioned cell media..." (column 22, lines 4-9). For instance, the conditioned medium of Naughton et al. may be used in the treatment of broken bones (column 22, lines 27-31). Therefore, limitations recited in claims 4, 5, and 14 (culture medium for treatment of bone tissue defects wherein broken bone is a defect associated with osteoporosis, spinal fixation procedure, joint replacement procedure, bone fracture; growth factors present in culture medium) are taught by Naughton et al. In order for the conditioned medium to be used for the treatment of tissue defects, the conditioned medium must be delivered to the site of said tissue defects. Further still, the conditioned medium may be formulated with a pharmaceutically acceptable carrier (column 5, lines 17-19) and the conditioned medium may contain collagens (column 25, lines 48-52), thus the limitations recited in instant claims 11 and 12 are disclosed.

Naughton et al. differs for the claimed invention in that it does not expressly disclose that the tissue culture for preparing the conditioned medium is subjected to an electromagnetic field.

Baylink discloses that "...the production of growth factor can be increased in vivo by the exogenous stimulation of living tissue with magnetic fields" (column 1, lines 53-55). Baylink teaches stimulating the production of growth factor in living tissue by the application of a magnetic field (abstract). The magnetic field may be applied with an electromagnet (column 6, lines 50-51), and thus Baylink teaches the application of electromagnetic fields for enhanced growth factor production. Baylink emphasizes that "it is to be understood that the method of the present invention is suitable for use in stimulating growth factor in a range of living tissue, including but not limited to in vitro cell cultures, animal subjects, or human subjects" (column 5, lines 28-32).

George et al. discloses the use of an electromagnetic field of specified strength and duration "...to stimulate cellular growth and proliferation,...growth factor expression,...and reductions in cell doubling time" (column 9, lines 12-17). George et al. accomplishes this by the administration of pulsed electromagnetic energy to cells (column 10, lines 4-7).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have applied an electromagnetic field, such as a pulsed electromagnetic field, to the tissue culture during incubation and prior to the extraction of the conditioned medium when performing the Naughton invention. One of ordinary skill in the art would have been motivated to do this since the application of an electromagnetic field would have increased growth factor production, thus resulting in a conditioned medium with a higher concentration of growth factors. Increased growth factor concentration is desirable since growth factors found in the conditioned media of Naughton et al. are for the treatment of tissue damage, regulate growth and differentiation, and accelerate wound healing (column 22, lines 4-26). Moreover, higher growth

factor concentration is sought after by Naughton patent since it points out that the conditioned medium "...may be further processed to concentrate or reduce one or more factors or components contained within the medium. For example, the conditioned medium may be enriched with a growth factor..." (column 5, lines 23-28).

The references also differ from the claimed invention in that Baylink or George et al. do not teach that the electromagnetic field is applied to the tissue culture for at least about 8 hours. Moreover, in the case of Baylink, there is no teaching that the electromagnetic field is pulsed.

Guerkov et al. teaches cell cultures incubated under pulsed electromagnetic field stimulation for 8 hours per day for 4 days (page 269, first full paragraph). There was an increase in transforming growth factor β1 production (page 273, last paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have applied a pulsed electromagnetic field for various periods of time, including administering it for 8 hours per day for 4 days as disclosed in Guerkov et al. One of ordinary skill in the art would have been motivated to have increased the length of time of exposure to a pulsed electromagnetic field since it would have yielded the predictable result of increasing growth factor production. Growth factors allow for repair and/or regeneration of tissue defects or damage, thus a higher concentration of growth factors in the conditioned media is desirable.

A holding of obviousness is clearly required.

Claims 1, 3, 9, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipley et al. (WO 93/04164) in view of Baylink and/or George et al and further in view of Guerkov et al.

Shipley et al. discloses a method to produce human keratinocyte-derived conditioned medium factors (kdCMF) wherein "...human epithelial cells are cultured in protein-free medium to obtain a conditioned medium and recovering the conditioned medium from the culture" (page 3, lines 30-35). Shipley et al. notes that "in its simplest form, the kdCMF of the invention is simply the conditioned medium harvested from such cultures" (page 5, lines 28-30). The kdCMF is used to promote healing of surface wounds, ulcerations, and other hypoproliferative skin pathologies (page 4, lines 1-5), and the kdCMF is applied to surface wounds with various pharmaceutically-acceptable carriers, including collagen (page 10, lines 8-27, particularly line 25). Thus, limitations recited in instant claim 12 are taught by the reference. It is noted that the kdCMF comprises a mixture of growth factors which provides efficacious results when applied to a wound in terms of increasing the rate of wound healing (page 4, lines 17-20).

Shipley et al. differs for the claimed invention in that it does not expressly disclose that the tissue culture of kerotinocytes for preparing the conditioned medium (kdCMF) is subjected to an electromagnetic field.

Baylink discloses that "...the production of growth factor can be increased in vivo by the exogenous stimulation of living tissue with magnetic fields" (column 1, lines 53-55). Baylink teaches stimulating the production of growth factor in living tissue by the application of a magnetic field (abstract). The magnetic field may be applied with an electromagnet (column 6, lines 50-51), and thus Baylink teaches the application of electromagnetic fields for enhanced

growth factor production. Baylink emphasizes that "it is to be understood that the method of the present invention is suitable for use in stimulating growth factor in a range of living tissue, including but not limited to in vitro cell cultures, animal subjects, or human subjects" (column 5, lines 28-32).

George et al. discloses the use of an electromagnetic field of specified strength and duration "…to stimulate cellular growth and proliferation,…growth factor expression,...and reductions in cell doubling time" (column 9, lines 12-17). George et al. accomplishes this by the administration of pulsed electromagnetic energy to cells (column 10, lines 4-7).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have applied an electromagnetic field, such as a pulsed electromagnetic field, to the tissue culture during incubation and prior to the extraction of the conditioned medium when performing the Shipley invention. One of ordinary skill in the art would have been motivated to do this since the application of an electromagnetic field would have increased growth factor production, thus resulting in a conditioned medium with a higher concentration of growth factors. Increased growth factor concentration is desirable since growth factors found in the conditioned media of Shipley et al. are for the treatment of increasing the rate of wound healing (page 4, lines 17-20).

The references also differ from the claimed invention in that Baylink or George et al. do not teach that the electromagnetic field is applied to the tissue culture for at least about 8 hours. Moreover, in the case of Baylink, there is no teaching that the electromagnetic field is pulsed.

Guerkov et al. teaches cell cultures incubated under pulsed electromagnetic field stimulation for 8 hours per day for 4 days (page 269, first full paragraph). There was an increase in transforming growth factor β1 production (page 273, last paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have applied a pulsed electromagnetic field for various periods of time, including administering it for 8 hours per day for 4 days as disclosed in Guerkov et al. One of ordinary skill in the art would have been motivated to have increased the length of time of exposure to a pulsed electromagnetic field since it would have yielded the predictable result of increasing growth factor production. Growth factors allow for repair and/or regeneration of tissue defects or damage, thus a higher concentration of growth factors in the conditioned media is desirable.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed November 26, 2007, and April 21, 2008 have been fully considered but they are not persuasive. With respect to the enablement rejection, the applicant argues that the specification teaches various working examples that are representative of the breadth of the claimed subject matter. However, as noted in the previous office action, the examples are prophetic. No data has been provided to demonstrate that the examples are indeed working examples, including Example 3. Though prophetic examples do not make the disclosure nonenabling, undue experimentation is required to determine embodiments that are operable. As pointed out in MPEP 2164.08(b), "...claims reading on significant numbers of

inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative." The applicant asserts that "These cells can be tissue specific, i.e. cells taken from or near the tissue defect, for example as a part of a biopsy that can have direct therapeutic effect to the defect where they were isolated." However, it is respectfully noted that the claims do not specifically narrow the treatment to a defect where the cells were isolated. Furthermore, applicant asserts that a great many tissue defects can be treated with a known cell culture or living tissue which provides regenerative or proliferative signals to many different types of cells that can be therapeutic for many different tissue defects. However, this assertion is not supported with evidence. As pointed out in MPEP 2145, section I, "The arguments of counsel cannot take the place of evidence in the record."

The applicant argues that Baylink and George does not anticipate claim 9 and its dependent claims since it fails to teach or disclose a composition that can be used to treat tissue defects comprising a medium produced by pulsed electromagnetic field radiation for at least 8 hours and a pharmaceutically-acceptable carrier. First, contrary to applicant's assertions, the compositions of Baylink and George indeed comprise a pharmaceutically-acceptable carrier as the DMEM medium is a solution and therefore a "pharmaceutically-acceptable carrier." It is noted that the recitation "pharmaceutically-acceptable carrier" can be broadly interpreted in its plain meaning. It is not limited solely to the exemplified embodiments, which are not specifically recited in the claims. Moreover, though DMEM medium may not be suitable for administration to subjects with equine and bovine product allergies, it is still suitable for all other subjects.

Furthermore, as pointed out above, although the reference does not specifically teach that the composition is effective for the treatment of tissue defects in a human or other animal subject, the compositions are the same, thus the claimed function must be inherent to the reference composition.

Also, instant claims 9, 10, 12, and 14 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of

the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). For these reasons, the compositions taught by Baylink and George anticipate the claims.

With respect to the 103 rejections, the applicant argues that Naughton fails to provide even one working example showing that any defect or even the presence of growth factors isolated from the conditioned media are capable of enhancing the proliferation of any cell type useful in any stated therapeutic application. Nevertheless, MPEP 2121, section I indicates that the prior art is presumed to be operable and enabling. While Naughton fails to teach irradiation of cell cultures with an electromagnetic field, Baylink and George are provided to teach that limitation.

The applicant asserts that that Baylink and George do not teach that the administration of electromagnetic field radiation is not in vitro. However, Baylink teaches that "it is to be understood that the method of the present invention is suitable for use in stimulating growth factor in a range of living tissue, including but not limited to in vitro cell cultures, animal subjects, or human subjects" (column 5, lines 28-32). Furthermore, George indeed teaches in vitro administration as it points out that biological cell proliferation was induced in vitro (column 9, lines 44-46 and 51-53). Therefore, there is no teaching away from the claimed invention.

While Baylink and George do not teach the claimed exposure time, this is rendered obvious by combination with the Guerkov reference, for the reasons discussed above. This also renders obvious the combination of the slow methods of Shipley with the fast methods of Baylink and George.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef